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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/00 — A1

(11) International Publication Number: WO 97/30638

(43) International Publication Date: 28 August 1997 (28.08.97)

(21) International Application Number: PCT/US97/02638

(22) International Filing Date: 21 February 1997 (21.02.97)

(30) Priority Data:
60/012,205 — 23 February 1996 (23.02.96) — US
08/733,798 — 18 October 1996 (18.10.96) — US

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(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

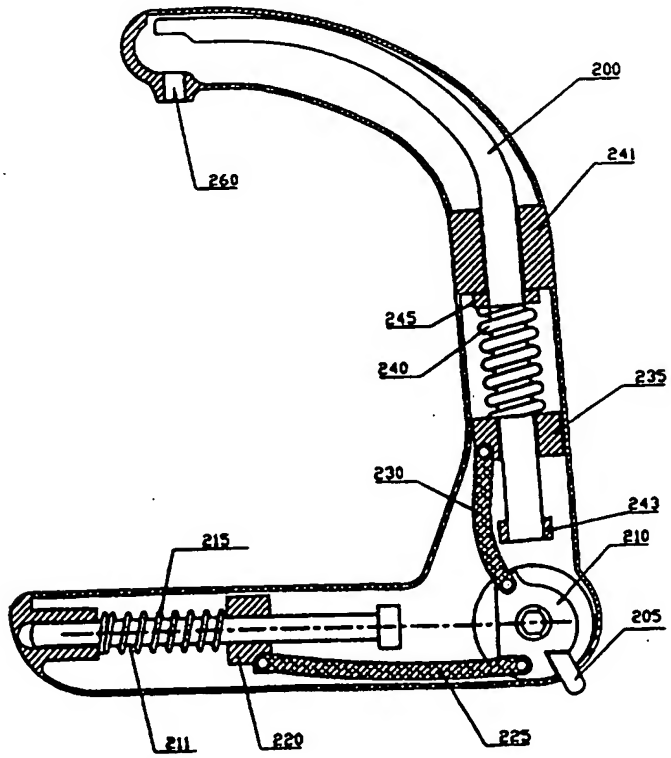
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: NON-LINEAR ANCHOR INSERTER DEVICE AND BONE ANCHORS

(57) Abstract

A power driven medical stapler and screw inserter device is formed in a non-linear or "C" or "V" shaped conformation. The non-linear shape allows the physician to accomplish a per vaginal anchor or screw insertion into a patient's pubic bone while locating the triggering hand outside of the vagina of the patient, and employing a pulling on the inserter/stapler against the pubic bone of the patient. The weight of a patient's body is used to counterweight the recoil effect to minimize stapler and screw recoil during the power driving of the staple or screw with suture into a patient. A spring power driven device is also shown. The bone anchor driver includes a hammer (200), a hammer guide (241), a main weight (235) driven by a main spring (240), a second weight (220) driven by a second spring (211), wherein the weights are used to drive the hammer.



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Non-Linear Anchor Inserter Device and Bone Anchors

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Field of the Invention

The present invention relates to a bone anchor, bone anchor screw, and an inserting device for use in medical applications, and particularly in medical suturing. The invention is especially useful in treating female urinary stress incontinence, although it can be utilized with other medical applications as well.

Background of the Invention and Description of the Prior Art

Urinary stress incontinence, i.e., the inability to control urination from the bladder, is a distressing problem for more than ten percent of elderly women as well as for many young women. This condition frequently arises in the following manner: in a normally anatomically positioned bladder, the proximal urethra and the bladder are in pressure continuity with the abdominal cavity, so that an increase in abdominal pressure is transmitted both to the bladder and to the proximal urethra, resulting in normal continence. However, particularly among elderly women, the bladder and the proximal urethra tend to descend from their normal anatomic positions such that the bladder neck and proximal urethra move away from the posterior wall of the pubic bone. When this occurs, the proximal urethra is no longer in pressure continuity with the abdominal cavity; therefore, an increase in intra-abdominal pressure (e.g. by laughing or coughing) results in an increase in intravesical pressure, but no change in the urethral closing pressure, thereby producing so-called stress incontinence. It also appears that as the bladder descends, the urethra becomes shorter and curved, so that its radial tonic muscle contraction is reduced, contributing to incontinence. Another pathology may arise from urethral sphincteric damage.

The surgical treatment for stress incontinence involves bladder neck suspension. One treatment is by an open surgical operation, involving an incision in the abdominal wall and/or anterior vaginal wall, to reposition and suspend the bladder and proximal urethra to their normal anatomic positions. This is done by suspension of the bladder neck and periurethral tissue to the posterior wall of the pubic bone. In another surgical procedure, the bladder neck is elevated by suspension of suture threads passing, with the aid of long needles, from both sides of the urethra and the bladder neck to the lower abdominal fascia or superior pubic bone ramus.

In prior U.S. Patent No. 5,520,700 (the disclosure of which is hereby incorporated by reference) apparatus and method(s) are disclosed which allow treatment of stress incontinence by incisionless per vaginal bladder neck suspension. As disclosed therein, an inserter device can be utilized for ejecting and implanting a staple or bone anchor through the vaginal tissue to enter the pubic bone. In another embodiment, as further discussed hereafter, an inserter device can be used to install a bone anchor by screwing the bone screw into the pubic bone, with or without vaginal incision. The suture thread that is secured to the bone anchor, staple or bone screw, suspends the bladder neck and the periurethral tissue to the posterior wall of the pubic bone.

It has been found, however, in stapler devices, and especially those that require high impact for bone implantation, that the ejection of the staple from the device causes the stapler to recoil. As is apparent from basic physics, the action of ejecting the staple from the stapler is associated with a reaction force which forces the inserter/stapler, and the hand of the individual (the physician) implanting the same, to move backwards. As a result, the physician must take this recoil into account and use force to firmly press the stapler against the pubic bone to ensure that the bone anchor is properly and effectively ejected and implanted. Anyone familiar with carpentry-type staple guns is familiar with this recoil. If pressure is not placed over the head end of the stapler, and the surface into which

the staple is driven is hard (as in the case of bone), the staple will not be fully implanted, but, rather, the user's hand will recoil. The medical stapler should also be held perpendicular to the bone surface. The stapler must be held in that position with the stapler held firmly during and through the ejection process so that the stapler does not shift its position as a result of the recoil. Otherwise, undue movement of the stapler because of recoil can result in a staple being ejected in an incorrect orientation, or incompletely ejected into the bone of the patient. This problem is especially apparent where the material into which the staple is ejected is bone and the physical confines of the space where the medical physician's hands are working is limited, i.e., within a vagina.

In U.S. Patent No. 3,580,313 issued May 25, 1971 to McKnight, a surgical instrument is described for attaching or anchoring body tissue to adjacent bone structure. Indeed, the specification (Col. 1, lines 29, et seq.) discusses use of the device for forcing staples through body tissue and into bone to correct stress incontinence. That device is a manual tool intended, according to the specification, to drive an anchor into bone to secure tissue thereto, through a small incision. The McKnight device requires that the staple be implanted by using the strength (or force) of the physician. In contrast, the present invention contemplates a mechanical, i.e., power-driven anchor inserter with suture and without incision or pre-drilling. The device of the '313 patent was not concerned with mechanical recoil whereas the present invention being power driven either in the ejector or screw embodiment, necessarily encounters mechanical recoil which is reduced by the C or V-shape of the device.

Similarly, where the inserter is a screwdriver type and the anchor is a screw type anchor, unless a hole is pre-drilled in the insertion site, constant firm pressure must be applied through the axis of the anchor (perpendicular to the pubic bone) to assist the self-tapping property of the anchor to facilitate insertion during screwing. The medical screwdriver type inserter must, therefore, be held

in the correct position relative to the patient's anatomy through the insertion process.

A purpose of the present invention is to provide a power driven anchor inserter device which provides leverage, facilitating a constant pressure at the anchor insertion site. This minimizes the effect of recoil during ejection of the anchor, increasing the ease of use of an inserter device in a medical procedure (whether a pusher or impact type inserter, or a screw inserter), and increasing the inserter device's effectiveness. This furthers the self-tapping property of the bone anchor, whether it be an impact type or screw type anchor.

A further purpose of the present invention is to provide leverage in the per vaginal insertion of a bone anchor into the pubic bone. The present invention allows the physician to employ a pulling force perpendicularly against the pubic bone of the patient, and to conveniently do so with one hand. The leverage, degree of accuracy and ease of insertion are believed to be significantly enhanced by the present invention.

In one embodiment, the invention relates to per vaginal bone screw insertion without drilling a hole in the bone by use of a non-linear or C-shaped inserter having a rotating intravaginal head for per vaginal bone screwing with or without vaginal wall incision. Additional purposes of the present invention are to provide screw type bone anchors and related devices and procedures for per vaginal incisionless or minimal incision bladder neck suspension.

Summary of the Invention

The present invention addresses the difficulties experienced in the prior art by providing a "C", "V" or other non-linear insertion shaped device for use in medical applications, and especially, per vaginal insertions of anchors of any type into the pubic bone of a patient. The insertion device, which may be rigid or flexible, is positioned during use so that force may be applied through the axis of the anchor. The weight of a patient can contribute to the force applied by the

physician to firmly press the device against the patient's anatomy, so as to minimize the effects of the problems normally associated with recoil. Although the present device is directed toward a stapler device for use to eject a staple type bone anchor, it will be appreciated that the pusher/driver portion of the device can alternatively be used to insert a screw type bone anchor and will be useful in other applications as well.

Accordingly, it is an object of the present invention to provide a power-driven insertion device which minimizes recoil during mechanical ejection of a bone anchor into bone.

It is further an object of the present invention to provide an insertion device which minimizes recoil during per vaginal insertion of a bone anchor having suture thread attached thereto into the pubic bone and otherwise allows constant pressure to be applied during the per vaginal insertion of self-tapping anchors into the pubic bone.

It is a further object of the present invention to provide a device which facilitates the application of additional pressure to the insertion site beyond the direct pushing pressure applied by the physician in the case of a linear inserter held in place in the vagina by the physician's hand. With the present inserter, the physician's hand is used to pull the inserter against the resistive force of the pubic bone, thereby forcing the anchor tip to penetrate the bone cortex. It is far easier to mechanically insert a bone anchor, staple or screw with the hands external to the vagina and by use of the pulling force perpendicular to the bone surface.

It is further an object of the present invention to provide an inserter device for medical applications which improves the accuracy and effectiveness of mechanical anchor insertions.

It is further an object of the present invention to utilize the physical pulling force on the inserter to further fixate the anchor tip penetration force perpendicular to the bone surface and in line with the physician pulling force.

It is further an object of the present invention to utilize at least a portion of the weight of a patient's body to maintain a bone anchor or screw inserter in firm contact with the patient during mechanical insertion of a bone anchor or screw into the patient's bone.

It is a further object of the present invention to use at least a portion of the weight of a patient as counter balancing leverage against the recoil of a bone anchor/staple/screw being mechanically inserted into the bone of a patient.

It is further an object of the present invention to provide an improved inserter device for inserting bone anchors, staples and/or screws in medical procedures.

It is further an object of the present invention to provide an improved bone anchor inserter for use in and to facilitate medical applications.

It is further an object of the present invention to provide improved bone anchors and bone anchor inserters.

It is further an object of the present invention to provide improved bone anchors and bone anchor inserters for treatment of female urinary stress incontinence and medical applications.

It is further an object of the present invention to provide an improved method for treatment of urinary stress incontinence.

It is further an object of the present invention to provide an improved method for treatment of urinary stress incontinence including per vaginal bone anchor insertion into the pubic bone. These bone anchors are either in the form of staples or screws. The bone anchor inserter has either a non-linear (e.g. a "C" or "V" shape) or linear shape and is operated either by an impact or by a rotational movement to insert or screw a bone anchor, staple or bone screw into the bone with or without vaginal wall incision.

Brief Description of the Drawings

Figure 1a is a side view of a stapler or pusher/impact type bone anchor inserter, in accordance with the present invention, with a front view of a loading key shown as well.

Figure 1b is a top, rear and side perspective view (on a different scale) of the stapler or pusher/impact type bone anchor inserter of Figure 1a.

Figure 1c is a cross-sectional view of a screwdriver-type bone anchor inserter for rotational insertion of bone screws, in accordance with the present invention.

Figures 1d(1) - 1d(6) are side views of various bone screws for use in the screwdriver-type bone anchor inserter of Figure 1c. Several different bone screw embodiments are shown, in accordance with the present invention.

Figure 1e is a cross-sectional view of a spring loaded C-shaped bone anchor inserter, having an alternative spring mechanism, in accordance with the present invention.

Figure 2 is a perspective view of a catheter inserted into the bladder of a patient in accordance with the method of the present invention, with a physician's (or health care worker's) two fingers partially inserted into a woman's vagina to locate the urethra and bladder.

Figure 3 is a perspective view of the hand of the physician pressing the anterior vaginal wall of a patient against the posterior of her pubic bone, according to the present method (again with a catheter in place).

Figure 4 is a perspective view of the bone anchor non linear inserter (in this case, a C-shaped inserter) inserted into the vaginal canal, with the anchor housing pressing the anterior vaginal wall of the patient against her pubic bone. Notice that the physician's hand, which is used for triggering the mechanism of the inserter, is outside of the vagina and that the physician can hold the inserter against the mechanical recoil force of the inserter. An enlarged inset cross-sectional view is provided of the insertion step, showing the bone anchor secured into the pubic bone with the attached suture.

Figure 5 is a perspective view of the hands of the physician tying the suture threads affixed to the bone anchors (the bone anchors having first been ejected or screwed, and implanted into the patient's pubic bone).

Figure 6 is a side perspective view of one form of a bone anchor used with the stapler/bone anchor inserter described herein.

Figure 7 is a top view of the stapler type bone anchor shown in Figure 6 which can be used with the staple inserter. In this figure, one example of a bone anchor with an offset tip is shown, i.e. a bone anchor in which the central, longitudinal axis of the tip is offset from the central, longitudinal axis of the bone anchor's shaft or body. An offset tip can be provided to a staple type bone anchor or to a screw type bone anchor.

Figure 8 is a top view of the curved shape that a bone anchor (e.g. that shown in Figures 6 or 7) achieves after insertion into bone, a consequence of it having been formed of shape memory alloy. Upon introduction into the patient, the temperature of the staple changes by its exposure to body heat (alternatively by removal of stress). The change in temperature causes the shape of the staple to change as well, in accordance with the properties of these alloys.

Detailed Description of the Drawings and the Preferred Embodiments

The present invention relates to an improved inserter device (whether a stapler or screw inserter) for inserting a bone anchor (whether staple or screw) into a patient. The inserter is shaped in a "C" shaped design which allows the physician's pulling force to initially press the staple or screw into the bone before and resists mechanical recoil during ejection or screwing of a bone anchor. As a consequence, the physician is able to use a pulling force against the resistive force of the pubic bone rather than a pushing force against the recoil of the mechanical inserter. The device also allows the physician to use the weight of a patient's body as counterbalancing leverage to minimize recoil of the staple during mechanical or power insertion, in contrast to manual ejection of a staple into the

patient's body. In addition, the novel geometry of the inserter allows the physician to hold the inserter and perform a per vaginal procedure with one hand located out of the vagina.

As shown in Figures 1a and 1b, a stapler or bone anchor inserter 10 is disclosed having a handle 15, finger trigger 20, anchor housing 25 and an anchor shield 30. Handle 15 is attached to body 55 of the bone anchor inserter 10. Body 55 is curved such that when attached to the handle 15 the two components form a "C" shaped apparatus. The inserter can be formed as a V-shape or another non-linear configuration.

In use, when the trigger is depressed, a drive or ejector pin (not shown, but located within the body) forces the anchor 35 (See Fig. 6, without suture thread shown, for ease of illustration) out of anchor housing 25, which is part of barrel 50 (see Fig. 1B) of the stapler 10. The stapler or bone anchor inserter 10 may be made of any suitable material, for example, stainless steel which meets surgical and sterilizable instrument standards. An internal spring mechanism (not shown) is in mechanical contact with the ejector pin (which is placed in contact with the bone anchor or staple 35). Upon the activation of the trigger 20, the ejector pin pushes the bone anchor or staple 35, providing the forcible ejecting, pushing and implanting of the bone anchor or staple 35, with attached suture thread, into bone. The ejection mechanism is activated by the trigger 20 which can be provided with a safety release or lock-out 42 to prevent accidental, premature staple discharge.

The tail end of the anchor 35 (best seen in Figures 6-8) is held in a nearly straight configuration within anchor housing 25 until ejection. The anchor housing 25 is attached to the inserter 10 prior to use, remains attached to the inserter during anchor insertion and, after insertion of the bone anchor, is removable and disposable. A new anchor and associated housing is then attached to the device for a subsequent use on the same patient (up to four anchors maybe used in bladder neck suspension) or the device sterilized for use with a next patient, prior to anchor and housing attachment. A retractable anchor shield 30 surrounds and

protects the sharp conical front end of the anchor, to ease precise location and insertion. The bone anchor 35 (the specific anchor 44 is shown in Figs. 6-8) is implanted into the bone without pre-drilling of a hole in the patient's bone. The bone anchor is self-tapping. After cocking or loading the internal spring mechanism using a loading key 40, which is placed into and rotated within loading socket 45, and attaching a bone anchor housing 25 (with a suture attached to an anchor 35 or 44), the bone anchor inserter 10 is ready for use. The spring mechanism stores the mechanical, i.e., power driving energy necessary to eject and insert the anchor directly into bone. In one preferred embodiment, this force of ejection is approximately 2.95 Joule $\pm$ 10%.

Figure 1c illustrates a C-shaped bone anchor driver in a shape allowing rotational insertion of a bone screw (with suture) into a bone, through a body orifice such as the vagina. The inserter consists of a handle 70 having a battery-operated motor 75 with a trigger switch 80 to control operation. The motor's rotational shaft movement is linked to a gear box (gear 81 and gear-to-shaft adapter 83) to allow more torque than originally provided by the motor. The force of rotation (torque) is transferred from the gear box through the inserter device to the screw adapter 90, via a flexible, rotatable shaft 95. A flexible shaft guide 97 may be provided around the shaft 95, as well, if desired.

The anchor is connected to screw adapter 90, which is at the second end of the inserter, the end opposite the grippable handle. The anchor or screw is disconnected from the adapter once the screw is implanted into the bone surface. A screw protector or retractable shield 100 shields the sharp tip of the screw until it is positioned, so as not to accidentally damage the patient's tissue during location. Once the inserter is precisely positioned, pulling the handle 70 retracts the spring-biased screw protector or retractable shield 100, thereby allowing the screw's sharp tip to initially penetrate the soft tissue. In another embodiment, the screw protector or retractable shield 100 may have a roughened edge surface, or small pins or sharp tips, to hold the soft tissue (such as vaginal mucosa) and to

prevent surrounding tissue rotation as the anchor screw rotates and penetrates the soft tissue and into the bone. Clearly, then, depressing switch 80 activates the motor 75 which drives the flexible shaft 95 connected to the screw adaptor 90. This causes a screw (see Figs. 1D) to become embedded into the bone.

Figure 1e shows an alternative, spring-loaded C-shaped inserter, having a different spring mechanism to that shown in Figures 1a & 1b. The inserter has a two spring mechanism which allows the user to impart more energy and impact to the anchor during implantation into the bone. At the same time, this inserter has the significant advantage that the two spring design results in cancellation of the rotational movement that the inserter may have during release. This results in a more stable anchor insertion.

This alternative inserter embodiment utilizes a hammer 200 which impacts and ejects an anchor into a bone. When safety or activating trigger 205 is not blocking the rotational movement of connecting cam 210, second spring 215 (located over holding rod 211) can longitudinally expand from its compressed state against slidable, doughnut-shaped second weight 220. This causes second rod 225 to rotate (counterclockwise in the drawing) connecting cam 210. Connecting cam 210 is also connected to main rod 230. Rotation of the connecting cam 210 in the counterclockwise direction of rotation by second rod 225, as shown in Figure 1e, moves main rod 230 downwardly or away from its first position, abutting against main (doughnut-shaped and slidable) weight 235. Since one end of main spring 240 is against hammer guide 241 (with friction disk 245 interposed) movement of main rod 238 allows main weight 235 to move downwardly against flange 243 of hammer 200. This causes the end of hammer 200 to impact a bone anchor.

More specifically, while main rod 230 is blocking main weight 235 from movement, the hammer 200 is maintained in a stationary "up" position and primed for subsequent downward movement to eject a bone anchor, held in recess 260. Main spring 240 is connected to main weight 235, with main weight 235 slidably

secured around hammer 200. A friction disk 245 is provided above the top end of main spring 240. A hammer guide 241 is provided around a portion of the hammer 200, as shown in Figure 1e and guides movement of the hammer. Before activation of the inserter, main spring 240 is maintained in a compressed position. Movement of main rod 230 away from main weight 235 (a consequence of rotation of rotation of connecting cam 210) allows main spring 240 to expand downward, forcing main weight 235 and hammer 200 rapidly downward. The release of the energy stored in main spring 240 thus forces hammer 200 to impact and eject a bone anchor out of recess 260 and into a bone.

The method of the present invention is shown in Figures 2-5. With the patient in lithotomy position, the surgical area and the vagina are cleaned and disinfected. A Foley catheter is inserted inside the bladder, and the balloon is inflated with approximately 10-20 cc of water. The catheter is then pulled outwardly to locate the balloon just above the bladder neck as shown in Figure 2.

The catheter (within the urethra) and the balloon at the bladder neck are palpated by the physician's finger tips. Pressing the fingers upwardly and forwardly, the anterior vaginal wall is pressed against the posterior pubic bone surface, as shown in Figure 3.

The bone anchor inserter (whether of the stapler/impact or screwdriver-type inserter) is then inserted into the vagina (see Figure 4) near the bladder neck and approximately 2 cm. to the side of the urethra. The inserter is pulled against the pubic bone. Notice that the triggering hand of the physician is external to the vagina and that the force applied by the physician is one of pulling against the resistive force of the pubic bone. The tip of the bone anchor 35 (as the anchor or screw protector retracts) touches and penetrates the vaginal wall and, upon ejection and implantation, enters the cortex of the pubic bone.

Thus, once the inserter is stable and properly positioned in the vagina, the trigger 20 (or switch 80, for the screw inserter of Fig. 1C; safety or activating trigger 205 of the device of Figure 1e) is pulled and the bone anchor 25 penetrates

and fixates within the bone. When the end of the inserter 10 is located on pubic bone, and pressed against it, the physician pulls up on the handle 15 of the stapler or bone anchor inserter 10. By doing so, the physician lifts the anchor 35 or screw 120 and anchor housing 25 or screw adaptor 90 against the pubic bone. A portion of the weight of the patient resists the lifting of the inserter, pressing against it firmly. As a result, the lifting of the stapler or bone anchor inserter 10 is performed against some of the weight of the patient, ensuring a firm and effective contact of the anchor tip with the pubic bone. Mechanically, it is easier for the physician to pull on the inserter with his or her hand outside of the vagina and to resist the power drive recoil of the device than for the physician to have his or her triggering hand within the vagina and pushing the inserter against the pubic bone. The penetration of the tip of the bone anchor into the bone cortex, before ejection or screwing further, increases the stability of the ejection into the pubic bone. The use of the C-shaped inserter allows at least part of the patient's weight to counterbalance the recoil of the power drive mechanism. The patient's body weight, along with the inserter's shape, provides the physician with suitable leverage for ensuring penetration of the anchor 35 or screw 120 into the pubic bone. This is especially important in the use of the present bone anchor device which, in the case of the power driven ejected anchor, seeks to avoid pre-drilling of a hole, followed by a separate step of anchor insertion.

Releasing the safety 42 first and then pressing the trigger 20 of the device activates the inserter spring mechanism which ejects the anchor 35 to a prescribed depth within the bone (e.g. 2.5 mm) so that little or no portion of the anchor protrudes from the bone surface. Although the end of the inserter will experience a reaction or recoil force when the staple is ejected, the weight of the patient, pressing downward against the inserter end (anchor housing 25 and anchor shield 30) combined with the force exerted by the physician by pulling the handle 15 of the bone anchor inserter 10 upward (so that the end of the inserter is forced against the weight of the patient and the penetration of the tip of the anchor into

the pubic bone before ejection) result in a firm and solid contact between the inserter and the pubic bone during and through the insertion process, minimizing any problems of insertion associated with power driven stapler recoil.

Two to four anchors are preferably inserted into the patient. Bone anchors are inserted on each side of the urethral axis or parallel along each side of the posterior aspect of the superior pubic bone ramus, lateral to the symphysis pubis. When four bone anchors are used, two bone anchors are inserted on each side of the urethral axis or parallel along each side of the posterior aspect of the superior pubic ramus, about 2 cm. lateral to the symphysis pubis. Each pair of two bone anchors is inserted, with the two bone anchors in a pair approximately 2 cm. apart. Cystoscopy is then performed to verify that there are no bladder or urethral perforations.

The suture threads extending from the anchors are then tied. For example, when inserting four bone anchors, four sets of suture threads should protrude from the vaginal wall. The suture threads are tied from one bone anchor to the other, ipsilaterally on each side of the urethra, as shown in Figure 5. They may be tied either above the vaginal mucosa or below the vaginal mucosa (using a deshamp) with or without vaginal dissection. The tie may be left as is or pushed beneath the mucosa.

Suprapubic or Foley urethral catheterization is then performed. The suprapubic catheter is to remain until complete bladder emptying is achieved by normal urination. Prophylactic antibiotic is administered perioperatively. Physical strain and lifting by the patient is to be avoided for approximately 2-3 months.

In one recommended embodiment, the bone anchor can be made of a single piece of a shape memory alloy, such as the nickel-titanium alloy called Nitinol. One form of bone anchor, for example, which can be used with the present invention, has a conical front end or tip 46 (See Figs. 6-8) with rear wall diameter ranging from 1.9-2.4 mm, and a tail end with a nearly rectangular cross-section. The tail end is preferably 6.0 mm long with a width that ranges from 1.9 - 2.4 mm

and a thickness of about 0.6 mm. The anchor tail 44 contains two holes 48 and 50 which are used for threading the suture. An example of a suture thread which can be used in the bone anchor is sterile polypropelene monofilament No. 1. The bone anchor is depicted in Figures 6 through 8. According to the preferred embodiment of the bone anchor 35, the longitudinal axis of the tail end is laterally offset from the center axis of the conical tip 46. This is best seen in Figs. 7 and 8. This allows the suture to be protected during the insertion process. Once driven within the bone medulla, the bone anchor 35 quickly heats to body temperature, changing, by shape memory alloy properties, for example, from a straight to a curved shape, i.e., the longitudinal axis of the anchor changes, after insertion. Alternatively, the shape memory effect can be accomplished by stress (holding it within the anchor housing) on the anchor and the subsequent removal of the stress. The shape of the anchor before insertion is shown in Figure 7, while Figure 8 shows the shape after it reverts to its austenitic condition.

According to one preferred embodiment, the end of the tail and the rear end of the conical tip, after heating of the bone anchor sufficient to change its shape, will subtend an angle of about 75° ± 16° (as seen in Fig. 8). This change of shape is because of the fabrication of the anchor from shape memory alloy. This curved shape ensures fixing the anchor within the bone and inhibits the inadvertent removal of the anchor. Pulling on the suture, which is connected to the anchor 35, causes the anchor to rotate and further fix in the bone. The reformation of the anchor to its curved shape (the shape it had prior to straightening) and rotation, together, prevent the anchor from exiting through the entrance path provided into the bone. The small profile and sharpness of the anchor tip 46 allow easy insertion inside the bone with minimal damage to the bone surface.

Thus, the present invention provides an apparatus and method which (in the anchor ejection or screwing mode) does not require pre-drilling of the bone or

soft tissue dissection to insert the bone anchor into the bone. Similarly, the bone anchor does not require cement or other fixative to remain in place.

The bone anchor and bone anchor inserter are supplied sterile. As the bone anchor inserter is a multiple use device, the inserter (and its loading key) should, of course, be cleaned and sterilized before each new patient procedure. Cleaning is accomplished by washing and rinsing the inserter and loading key with water and a liquid detergent, while scrubbing with a flexible brush to completely remove all traces of blood. The inserter and loading key should be rinsed thoroughly with water to remove detergent residues. Panels in the inserter body allow access for cleaning. Once cleaned, the inserter and loading key may be cloth or air dried. The inserter and loading key may be sterilized by heat or steam autoclave, or gas (EtO), in accordance with hospital procedures for sterilization of stainless steel surgical instruments.

Various different types of bone screws 120 can be used in accordance with the present invention. As shown in Figure 1d(1), a bone screw is disclosed having a conical tip 110 and a screw body 115. The diameter of each of the screw threads 128 (the grooves, recesses or indentations in the material of the screw) is constant along the length of the screw body. The suture 125 is attached at a single hole in the rear end 127 of the bone screw.

Figure 1d(2) shows a bone screw 120 with a more tapered conical tip 130 and screw body 135. In this version, the diameter of the screw threads 140 vary along the longitudinal axis of the screw. The diameters of the screw threads 140 increase from small diameters near the apex of the conical tip to greater diameters near the screw body 135. The screw threads 140 can be located on all or a portion of the screw body as well, if desired. The suture 150 is attached through a hole in the end 147 of the screw.

Figure 1d(3) is similar to Figure 1d(1). In this figure, however, the suture is shown attached through a hole in the middle 152 of the bone screw.

Figure 1d(4) shows a bone screw 120 in which the screw threads or grooves are formed by wrapping spring wire 156 around the solid body. The body has a leading tip 170 and a shaft 172, of smaller relative cross section. A trailing end 174 of increased cross section in comparison to the shaft, is provided with a hole for attaching the suture thread 176. The spring wire is wrapped on the shaft 172 and maintained between leading tip 170 and the enlarged trailing end 174.

Figure 1d(5) shows a bone screw similar to that in Figure 1d(4). In this screw, leaf springs 158 are provided. Leaf springs 158 are initially held against the side surface of the bone screw, i.e., before and as the screw is inserted into the bone. Upon insertion, however, the leaf springs 158 expand outwardly from their compressed to a non-compressed state (due to the elasticity which is characteristic of a spring) to provide greater anchoring of the bone screw within the bone.

Figure 1d(6) discloses a bone screw in which the screw threads or grooves are formed by wrapping a spring plate 163 around the screw body or shaft of the screw. Here, too, the spring plate is held between the enlarged surfaces of the leading tip and the trailing end. Upon insertion, the spring plate expands to hold the anchor in place in the bone.

The bone screw is typically made of a medical grade alloy such as Stainless Steel 316. Its sharp tip and small diameter allow for penetration through the vaginal wall and the periosteum, without pre-drilling a hole. As the screw is rotated by the inserter, which may be linear or C-shaped, it enters the bone until it reaches a prescribed depth within the bone. The screw then disconnects from the rotating inserter shaft. The medical technique of inserting a bone screw into the pubic bone through the vagina for the purposes of bladder neck suspension is also within the scope of the present invention, as is the bone screw inserter.

Having described this invention with regard to specific embodiments, it is to be understood that the description is not meant as a limitation since further variations or modifications may be apparent or may suggest themselves to those

skilled in the art. It is intended that the present application cover such variations and modifications as fall within the scope of the appended claims.

Claims

We claim:

1. A medical device for ejecting and installing a bone anchor with attached suture into a patient, comprising:

a handle;

a body, said body having a first end and a second end, said body being attached to said handle at said first end, said body and said handle together forming a non-linear shape;

an anchor housing, said anchor housing located at said second end of said body and being provided for holding a bone anchor; and,

a power means in communication with said anchor housing for providing driving power to the bone anchor.

2. A medical device as claimed in Claim 1, wherein said body and said handle form a C shape.

3. A medical device as claimed in Claim 1, wherein said body and said handle form a V shape.

4. A medical device as claimed in Claim 1, wherein said device is a medical stapler for forcibly ejecting and implanting a self-tapping bone anchor into the bone of a patient.

5. A medical device as claimed in Claim 1, wherein said device is a screw driving device for screwing a self-tapping bone anchor into the bone of a patient.

6. A system for pervaginal bone screw insertion, comprising:

a bone screw; and,

a non-linear screw inserter means for inserting said bone screw into a patient's bone, said inserter means comprising a first end having a handle and a second end having a retractable shield having sharp tips, said bone screw being held at said second end with said retractable shield protecting said bone screw, wherein pulling of said handle retracts said retractable shield and reveals said sharp tips, said sharp tips being used to hold the soft tissue of a patient surrounding said screw and preventing the soft tissue from rotation during the screwing of said bone screw through the soft tissue and into the bone.

7. A system as claimed in Claim 6, wherein said non-linear screw inserter is C-shaped.

8. A system as claimed in Claim 6, wherein said bone screw comprises a shaft comprising a leading tip and a trailing end, said shaft having screw threads, and said bone screw further having a suture secured thereto.

9. A system as claimed in Claim 8, wherein said bone screw further comprises leaf springs, said leaf springs expanding outwardly upon insertion of said bone screw into the bone of a patient to more securely fixate said bone screw in the bone.

10. A system as claimed in Claim 8, wherein said bone screw is made of shape memory material.

11. A system as claimed in Claim 8, wherein said suture is secured at a point about midway between said leading tip and said trailing end.

12. A system as claimed in Claim 8, wherein said suture is secured at said trailing end.

13. A system as claimed in Claim 8, wherein said bone screw is provided with threads comprised of wire wrapped around said shaft.

14. A system as claimed in Claim 8, wherein said leading tip is conical.

15. A system as claimed in Claim 8, wherein said leading tip of said bone screw and said shaft form a taper.

16. A bone anchor for fixation in the bone of a patient, comprising:
a tip portion, a screw body portion and a tail end, said screw body portion comprising screw threads and either said screw body portion or said tail end having at least one hole for attaching a suture.

17. A bone anchor as claimed in Claim 16, wherein said tip portion is conical.

18. A bone anchor as claimed in Claim 16, wherein said bone anchor comprises shape memory alloy.

19. A bone anchor as claimed in Claim 18, wherein said shape memory alloy is activated by stress and released by removal of said stress.

20. A bone anchor as claimed in Claim 18, wherein said shape memory alloy is activated and released by changes in temperature of said bone anchor.

21. A bone anchor as claimed in Claim 17, wherein said tail end is approximately 6.0 mm long and approximately 1.9-2.4 mm wide, is of a thickness of approximately 0.6 mm, and is of a nearly rectangular cross section, and wherein said conical tip has a base diameter of approximately 1.9-2.4 mm.

22. A bone anchor as claimed in Claim 16, wherein said tail end comprises at least two holes for securing said suture.

23. A bone anchor as claimed in Claim 16, wherein the central longitudinal axis of said tip is laterally offset from the central longitudinal axis of said screw body.

24. A bone anchor as claimed in Claim 18, wherein the longitudinal axis of said bone anchor changes from straight to a curved shape upon introduction into a patient's bone.

25. A bone anchor as claimed in Claim 18, wherein said bone anchor subtends an angle of approximately 59-91 degrees after changing shape upon introduction into a patient's bone.

26. A bone anchor as claimed in Claim 16, wherein said hole is located in said tail end.

27. A bone anchor as claimed in Claim 16, wherein said hole is located in the middle of said bone anchor.

28. A bone anchor as claimed in Claim 16, wherein the outer diameter of said screw threads vary over the length of said screw body portion.

29. A bone anchor as claimed in Claim 28, wherein said diameter is smaller near said tip and becomes larger near said tail end.

30. A bone anchor as claimed in Claim 17, wherein said screw threads increase from a small diameter near the apex of said conical tip to a greater diameter along the length of said screw body portion.

31. A bone anchor as claimed in Claim 16, wherein at least some of said screw threads are located on said screw body portion, and wherein the diameter said screw threads is constant along the length of said screw body.

32. A bone anchor as claimed in Claim 16, wherein said screw threads are provided along substantially the entire length of said screw body portion.

33. A bone anchor as claimed in Claim 16, wherein said screw threads comprise a wire wrapped around said bone anchor.

34. A bone anchor as claimed in Claim 16, wherein said screw body comprises a shaft, and said shaft is of smaller relative cross section than said tip.

35. A bone anchor as claimed in Claim 16, wherein said bone anchor comprises at least one leaf spring, said leaf springs being capable of changing shape from a compressed to a non-compressed condition.

36. A bone anchor as claimed in Claim 16, wherein said screw threads are formed by wrapping a spring plate around said screw body.

37. A screw-type anchor inserter comprising:

a) a handle;

b) a body connected to said handle, said handle and body forming a non-linear shape;

c) a screw-holding adapter means secured to said body; and

d) a power drive means in said handle or body for providing rotational torque to said screw-holding adapter means.

38. An inserter as claimed in Claim 37 wherein said power drive means comprises a finger-operated trigger means.

39. An inserter as claimed in Claim 37 wherein said power drive means comprises a flexible rotating drive shaft extending between said handle and said screw holding adapter means.

40. An inserter as claimed in Claim 37 wherein said power drive means comprises:

a) an actuating trigger means;

b) a motor electrically connected to said trigger means and having a rotating shaft;

c) electric generating means connected to said motor to drive said rotating shaft when said trigger means is activated; and

d) a flexible, rotating drive shaft extending between said rotating shaft of said motor and said screw-holding adapter means.

41. An inserter as claimed in Claim 40 further comprising torque enhancing means to increase the rotational torque of said flexible shaft in comparison to the torque of said rotating shaft of said motor.

42. An inserter as claimed in Claim 37 wherein said screw-holding adapter means is selectively, replaceably secured to said body.

43. An inserter as claimed in Claim 37 further comprising a screw protector housing for said screw-holding adapter means.

44. An inserter as claimed in Claim 43 wherein said housing is retractable.

45. An inserter as claimed in Claim 43 wherein said housing retracts when said housing is in perpendicular contact with the tissue of a patient.

46. An inserter as claimed in Claim 45 wherein said housing is spring biased to protect said screw-holding adapter means.

47. A medical bone anchor inserter comprising:

a) a handle;

b) a body connected to said handle, said handle and body forming a non-linear shape;

c) a staple-holding head secured to said body;

d) a power drive means in said body for providing driving force to said staple holding head.

48. An inserter as claimed in Claim 47 wherein said power drive means is a spring loaded, hammer means and an activating trigger for selectively releasing said hammer means.

49. An inserter as claimed in Claim 48 wherein said hammer means comprises a reciprocating hammer rod; a first spring held on one end against a hammer rod guide in said body; an annular first weight slidable over a portion of one end of said hammer rod; said weight being movable over said hammer rod by contact by said second end of said spring; and said hammer rod having a flange which is contacted by said first weight when said trigger is activated.

50. An inserter as claimed in Claim 49 wherein said hammer means is controlled by a second spring mechanism comprising:

a) a handle rod secured in said handle;

b) a second spring mounted on said handle rod and held in position on one of its ends; and

c) a slidable, annular second weight connected to said second end of said spring.

51. An inserter as claimed in Claim 47 wherein said activating trigger comprises:

a) a trigger device;

b) a connecting cam rotatable about a pivot point;

c) said connecting cam having a first rod extending therefrom and in contact with said first weight;

d) said connecting cam having a second rod extending therefrom and in contact with said second weight; such that with said triggering device, when in a first position, causes said first and second rods to maintain said first and second spring mechanisms in their compressed state and when said triggering device is moved to a second position, said first and second rods allow said first and second spring mechanisms to achieve their expanded state, thereby moving said respective first and second weights and in so doing causing said hammer rod to drive a staple.

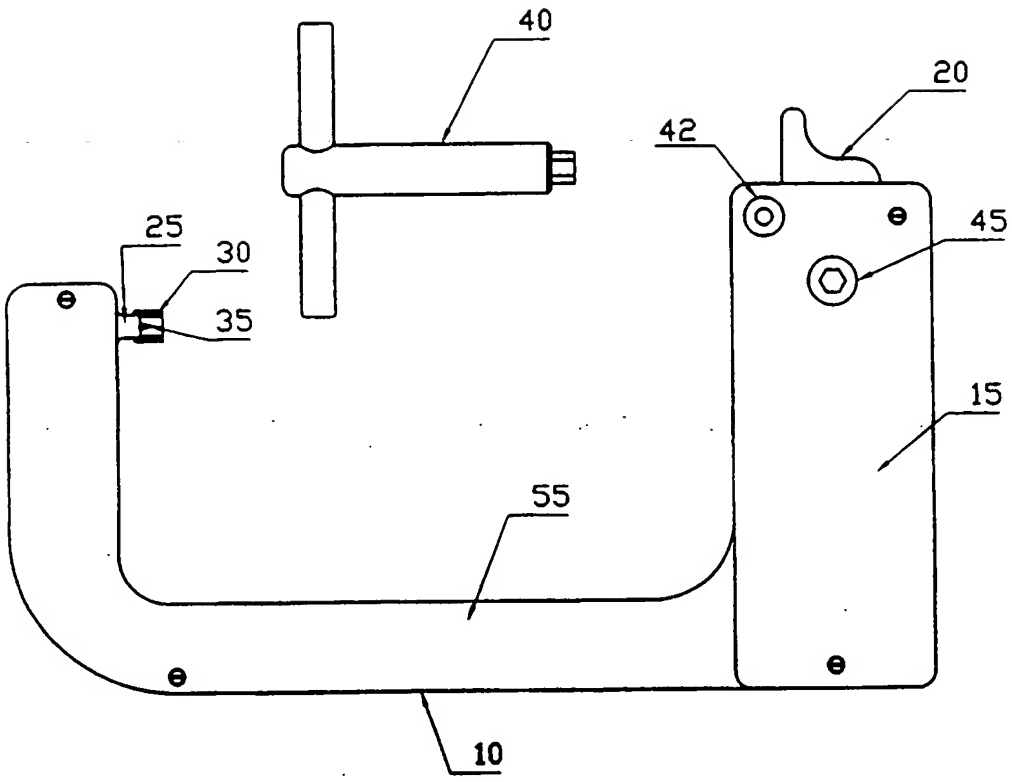

Fig. 1A

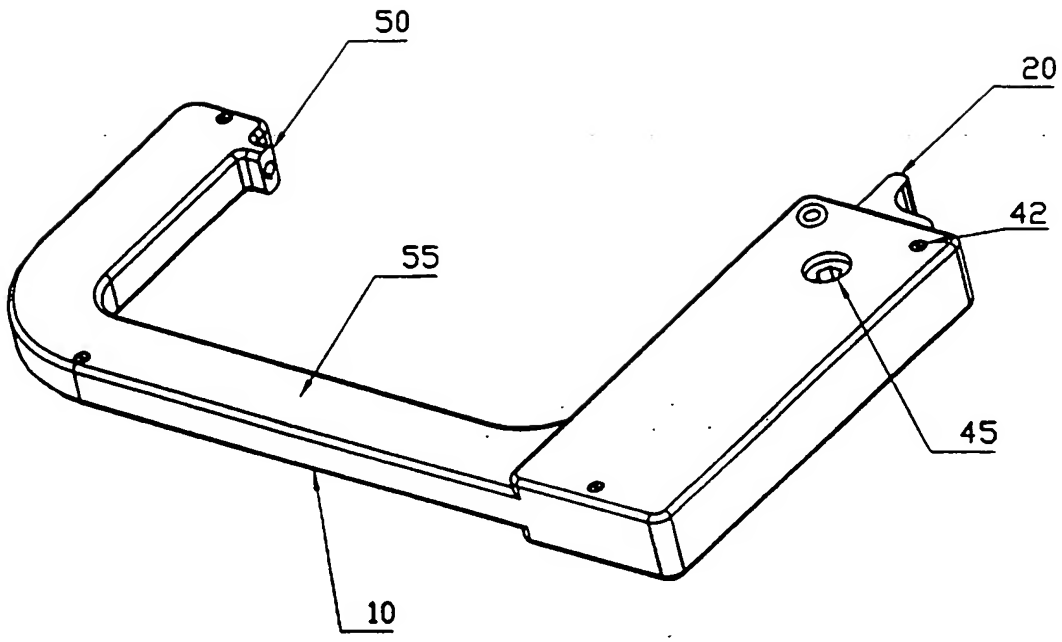

Fig. 1B

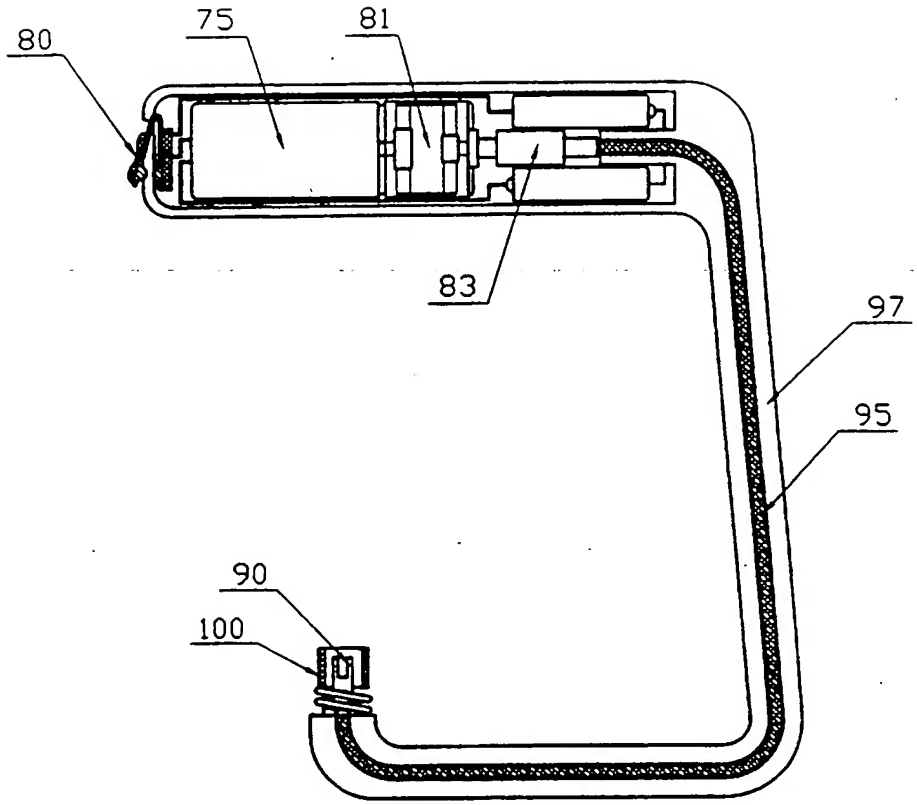

Fig. 1C

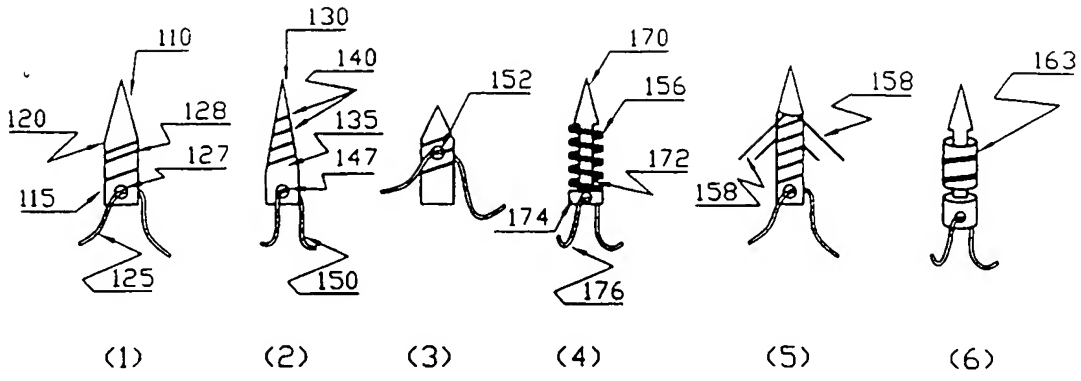
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Fig. 1D

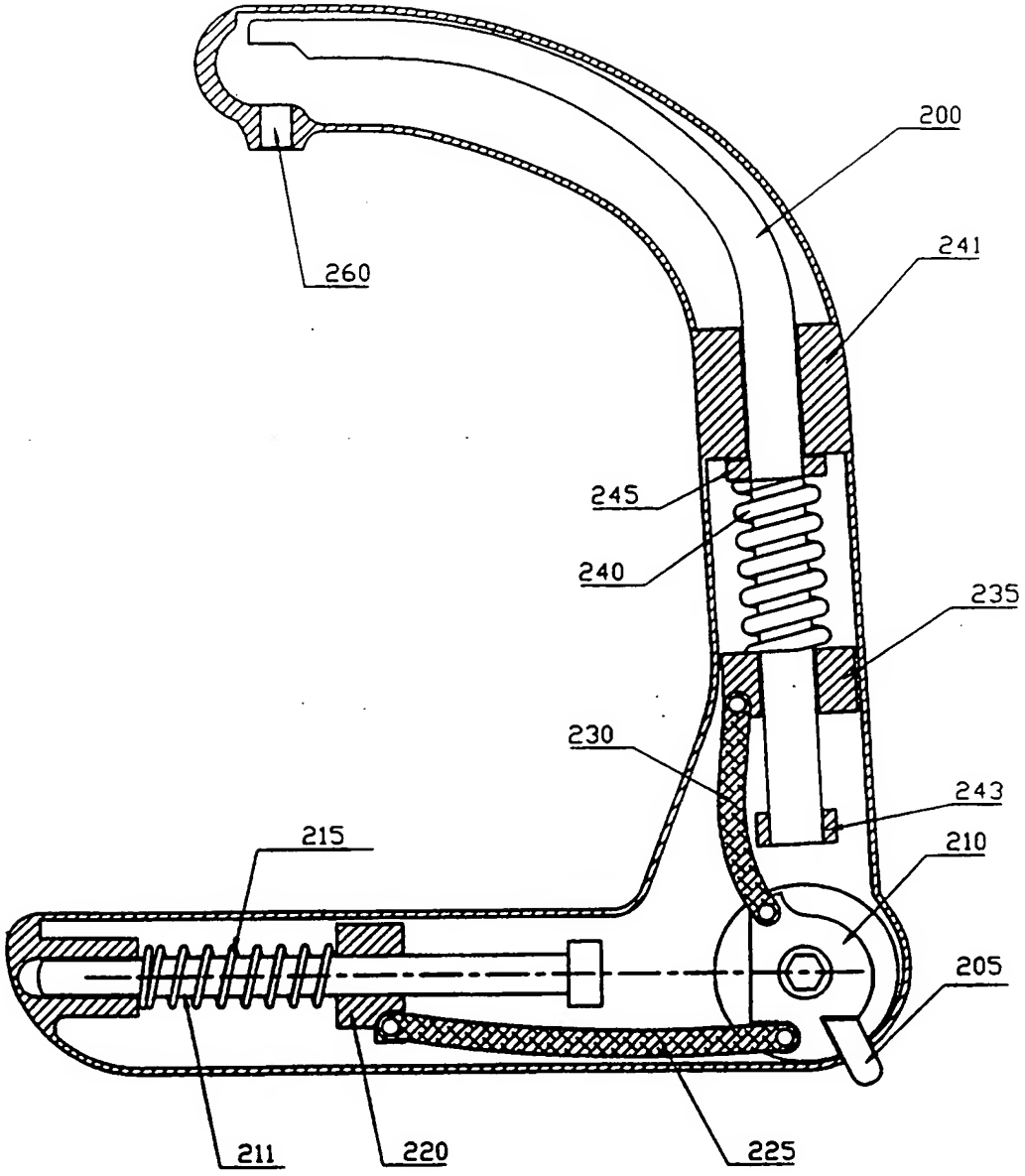

Fig. 1E

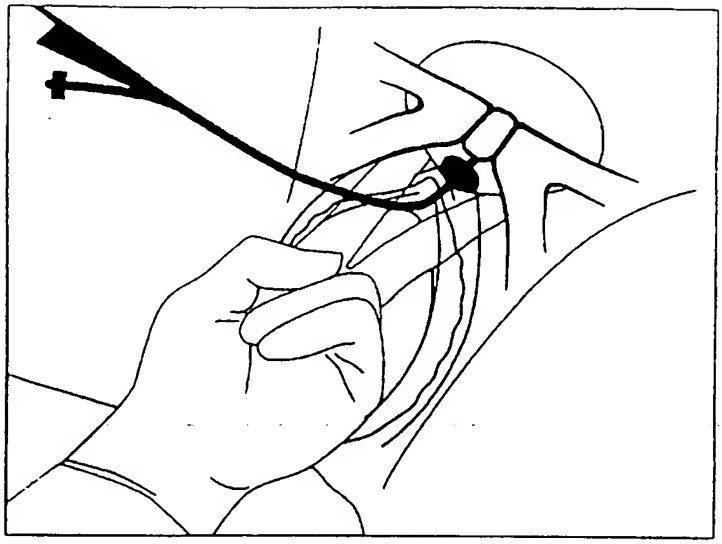

Fig. 2

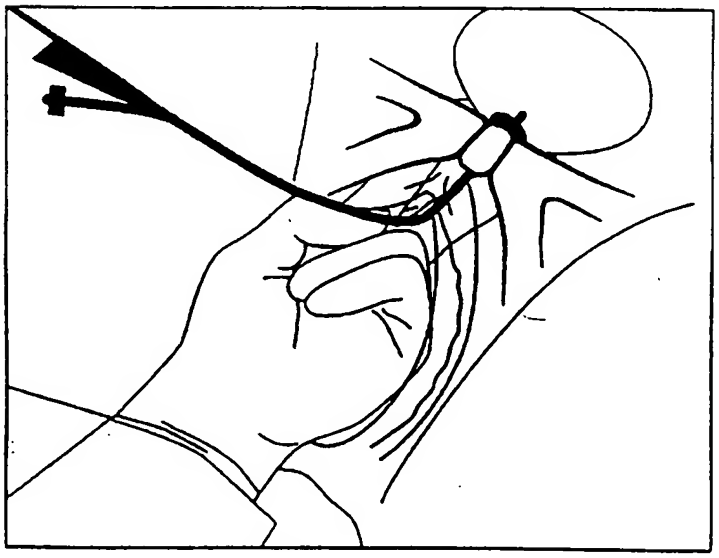

Fig. 3

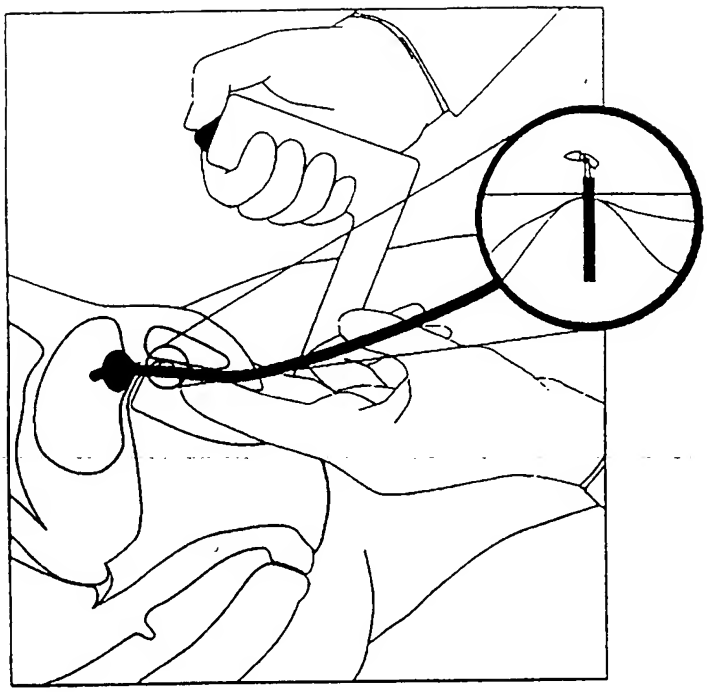

Fig. 4

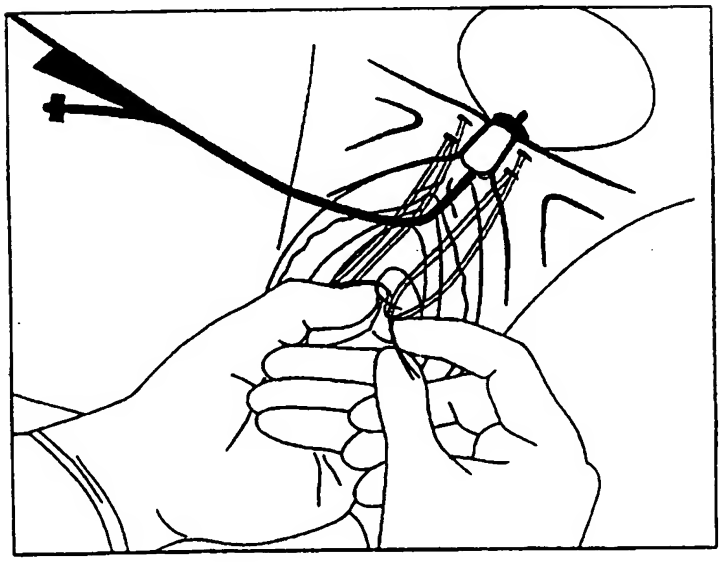

Fig. 5

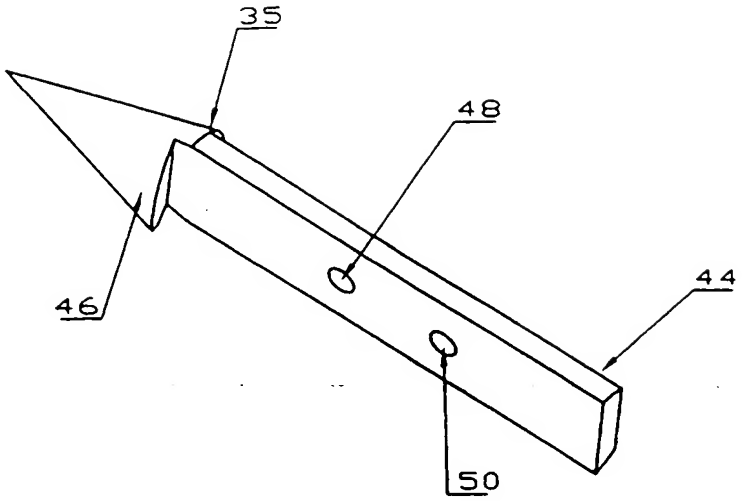

Fig. 6

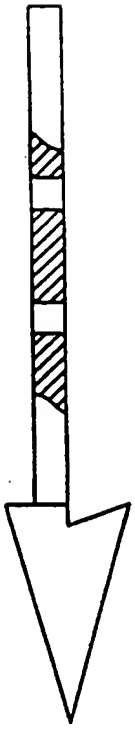

Fig. 7

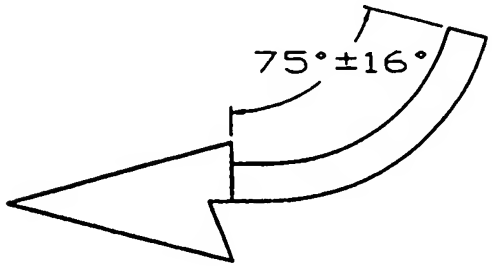

Fig. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US97/02638

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 17/00
US CL :606/142
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/104, 149, 142, 143, 232

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	us 5,370,662 A (STONE et al) 06 December 1994, entire document.	16, 17, 21, 22, 26, 27, 31, 32
Y,P	US 5,520,700 A (BEYAR et al) 28 May 1996, entire document.	1-4, 47
Y	US 5,464,407 A (McGUIRE) 07 November 1995, Figs. 6-9.	1-4, 47

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 12 JUNE 1997	Date of mailing of the international search report 26 JUN 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JEFF SCHMIDT Telephone No. (703) 308-3141

Form PCT/ISA/210 (second sheet)(July 1992)*